RESPONSE

I. Status of the Claims

Claims 1 and 6 were previously cancelled entirely without prejudice and without disclaimer. Claim 2 has been currently amended. Claims 2-5 and 7-11 are presently pending in the case.

II. Support for Amendments

Claim 2 has been amended to more clearly claim certain aspects of the present invention. Amended Claim 2 finds support in the specification, claims and sequence listing as originally filed with particular support being found on page 4, line 34 of the specification.

III. Rejection of All Claims Under 35 U.S.C. § 101

The Non-Final Action maintains the rejection of the claims under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants disagree and respectfully maintain their traverse as presented in their previous response (Paper No. 7 which is herein incorporated in its entirety).

The Non-Final Action discounts many of the numerous utilities described in the specification for the sequences of the present invention based on the position that while credible, these utilities are not specific or substantial. While Applicants in no way agree with the Examiner's arguments, Applicants have chosen to expand on only a few of the utilities as only one is required.

Applicants respectfully submit that the legal test for utility involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

In *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the

requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Even under the newly installed utility guidelines, Applicants note that MPEP 2107 (II)(B)(1) states:

> (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (MPEP 2107 (II)(B)(1))

Applicants would first like to invite the Examiner's attention once again to the fact that a sequence that is greater than 97% identical at the amino acid level to SEQ ID NO:20 of the present invention is present in GenBank, the world's largest repository of such information. This protein, GenBank accession number Q8WXS8, has been annotated by third party scientists, *wholly unaffiliated with Applicants*, as encoding a "ADAMTS-14 precursor (A disintegrin and metalloproteinase with thrombospondin motifs 14) (ADAM-TS 14)" (amino acid alignment, description and GeneBank report provided in Applicants' previous Response (Paper # 12) as Exhibits B and C).

The claimed sequences were described in the specification as being similar to metalloproteinases, especially zinc metalloproteases of the ADAMTS family (page 18, lines 30-31 and page 2, lines 4-5). These statements assert that the sequences of the present invention and zinc metalloproteases of the ADAMTS family share a similarity in structure, a similarity in function and thus a recognized similarity in biological function. This position would be readily accepted by those of skill in the art, as it is generally recognized that there is a structure-function relationship. Absent any evidence of record that the described human metalloproteases somehow fails to function as does zinc metalloproteases of the ADAMTS family, the Examiner has failed to meet his/her burden of establishing that the Applicants' assertion of protein function is not credible. Accordingly, the Examiner is respectfully requested to either provide evidence that substantially and specifically refutes the Applicants' asserted function/utility, or withdraw the rejection. Clearly, the sequences of the present invention have patentable utility and pending rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph should be withdrawn. his provides clear and convincing evidence that those of skill in the art would recognize Applicants' assertions that the claimed sequences encode a metalloprotease, more specifically a zinc metalloprotease known as ADAMTS14, as credible.

The function and utility of ADAMTS14 is described in the scientific publication entitled "Characterization of ADAMTS14, a novel member of the ADAMTS metalloproteinase family" by Bolz *et al.* (Biochim Biophys Acta. *1522*:221-5, 2001, abstract provided in Applicants' previous Response (Paper #12) as Exhibit D)and in a second publication entitled "Cloning and characterization of ADAMTS-14, a novel ADAMTS displaying high homology with ADAMTS-2 and ADAMTS-3" by Colige, *et al.*, 2002 (J Biol Chem. *277*:5756-66, 2002, which was Published 2001 Dec 07, abstract provided in Applicants' previous Response (Paper #12) as Exhibit D and the entire publication submitted herewith as **Exhibit 1**).

Applicants have previously submitted as evidence publications supporting Applicants' assertions that the claimed sequences encode a novel human ADAMTS zinc metalloprotease (ADAMTS14) and that this zinc metalloprotease has a recognized utility. Furthermore, others have recently confirmed and published evidence in support of Applicants assertion regarding the utility of the claimed invention in arthritis and connective tissue disorders, as stated in the specification as filed on page 12, line 34). In a publication entitled "Expression profiling of metalloproteases and their inhibitors in cartilage" Kevorkian L, *et al.*,(Arthritis Rheum 50(1): 131-141: 2004 abstract provided herewith as **Exhibit 2**) the expression of ADAMTS14 was shown to be significantly increased in cartilage of human patients with osteoarthritis. This third party evidence clearly supports the credibility of Applicants' assertions in the specification that the sequences of the present invention have real world utility in regards to human disease, specifically as stated in the specification these sequences have utility with regard to human arthritis and connective tissue disorders. Thus, clearly Applicants' assertions regarding the utility of the claimed sequences in diagnostic and prognostic assays as described in the specification is a valuable and credible utility. Therefore, clearly, there can be no question that the claimed sequences of the present invention have a specific, substantial, well-established and real world utility. The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given this GenBank annotation and the described publications, there can be no question that those skilled in the art would clearly believe that the molecule encoded by the sequences of the present invention have specific, substantial and well established utility. As such, the scientific evidence clearly establishes that Applicants have described an invention whose utility is in full compliance with the provisions of 35 U.S.C. § 101, and therefore Applicants respectfully request withdrawal of the rejection.

If, somehow, the above arguments were not deemed sufficient, it must again be noted that the rejection of the present invention due to lack of patenatable utility also runs contrary to Example 10 of the PTO's Revised Interim Utility Guidelines Training Materials (pages 53-55), which establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, is not proper when there is no reason to doubt the asserted utility of a full length sequence that has a similarity score of 95% to a protein having a known function. In the Analysis portion of Example 10 it states that "Based on applicant's disclosure and the results of the PTO search, there is no reason to doubt the assertion that SEQ ID NO:2 encodes a DNA ligase. Further DNA ligases have a well-established use in the molecular biology art based on this class of proteins ability to ligate DNA. .....Note that if there is a well-established utility already associated with the claimed invention, the utility need not be asserted in the specification as filed..... Thus the conclusion reached from this analysis is that a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph, utility rejection should not be made."

In the present case, clearly evidence supports Applicants' assertions that the sequences of the present invention encode human zinc metalloproteases of the ADAMTS family, specifically ADAMTS14, a protein for which there is a well-established utility that is recognized by those of skill in the art. Thus, based on applicant's disclosure and the evidence presented, there is no reason to doubt the assertion that SEQ ID NO:20 encodes a human ADAMTS zinc metalloprotease and is involved in human arthritis and connective tissue disorders. The present case is thus identical to that presented in Example 10 of the Revised Interim Utility Guidelines Training Materials (pages 53-55). In the present case it is clear that the sequences of the present invention encode novel human zinc metalloproteases of the ADAMTS family with greater than a 95% identity to a protein having a known function (ADAMTS14). However, even if, *arguendo*, Applicants had failed to assert this utility, according to the guidelines "Note that if there is a well-established utility already associated with the claimed invention, the utility need not be asserted in the specification as filed...Thus the conclusion reached from this analysis is that a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph, utility rejection should not be made"(emphasis added). Thus, the present rejection of the presently claimed invention under a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph utility rejection should not have been made and should be withdrawn.

In the Non-Final Action, the Examiner tries to make a distinction between the DNA ligases in Example 10 of the Utility Guidelines, as a class of proteins whose function is known and the ADAMTS zinc metalloproteases of the present invention. ADAMTS zinc metalloproteases have a well established utility, furthermore the function of the specific ADAMTS zinc metalloprotease encoded by the claimed sequences ADAMTS14 is known to those of skill in the art and has a human disease association.

The above presented evidence counters the Non-Final Action's suggestion that Applicants knew of no specific, substantial or well-established utility at the time the application was filed. The Non-Final Action suggests that the claims lack utility "because the specification has no disclosure of a specific *in vitro* utility for the isolated nucleic acids .... (page 2 lines 23 through page 3 line 2). Indicating a need for such information is misplaced for it has long been established that "there is no statutory requirement for the disclosure of a specific example". *In re Gay*, 135 USPQ 311 (C.C.P.A. 1962).

However, the specification in fact detailed a number of specific utilities for the presently claimed polynucleotide sequences, among these were, use in diagnostic assays (see, for example, the specification at page 4, line 22 and page 18, line 21), identification of protein coding sequence and identification of exon splice junctions (see, for example, specification at least at page 11, lines 11-16). The claimed sequence also have specific and substantial utility in mapping the position of human ADAMTS zinc metalloprotease to a specific region of a human chromosome, see for example, the specification at page 3, line 5, and as was exemplified in Applicants' previous Response (Paper #12) as Exhibit E, in which it was shown that the claimed sequence of SEQ ID NO:19 could be used to map the present ADAMTS zinc metalloprotease to the very same location that others now recognize as encoding ADAMTS14, human chromosome 10 (at approximately 10q2).

Additionally, the specification describes the use of the claimed sequences in assessing gene expression patterns, particularly using a high throughput "chip" format (see, for example, the specification at page 6, line 4 through page 8). The above described publication entitled "Expression profiling of metalloproteases and their inhibitors in cartilage" Kevorkian L, *et al.*,(Arthritis Rheum 50(1): 131-141: 2004) clearly and specifically demonstrates the validity of Applicants assertions regarding the utility of the claimed sequences in expression analysis, and particularly that of the

present ADAMTS zinc metalloprotease in association with human arthritis and connective tissue disorders, as were described in the specification as filed. Thus clearly, this third party evidence supports the credibility of Applicants' assertions with regard to the use of the claimed sequences in such *in vitro* assays, although not required, are multitude. Thus as described in the specification the sequences of the present invention have real world utility in regards to human disease, specifically as stated in the specification these sequences have utility with regard to human arthritis and connective tissue disorders. Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, a technology which the Examiner concedes has utility, then the presently claimed nucleotide sequence encoding human zinc metalloproteinase ADAMTS14, whose expression has been associated with human arthritis and connective tissue disorders, must also be useful and have utility. Accordingly, there can be no question that the described sequences provide an exquisitely specific utility for analyzing gene expression. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Finally, while the Non-Final Action argues that the present situation is analogous to *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), clearly it is not. The claimed sequences clearly encode a human ADAMTS zinc metallprotease, ADAMTS14 which has among its many specific, substantial, well-known and credible utilities been associated with human disease, an association described in the specification. Thus no hunting license is required to identify the utility of the claimed sequences which encode the human zinc metalproteinase, ADAMTS14, as several of the most recognized utilities are published and are evidenced in the exhibits that have been submitted in this case.

With full recognition of the fact that all patent applications are examined on their own merits and that the prosecution of one patent does not effect the prosecution of another patent, *In re Wertheim,* 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976), however the issue at hand in one of whether the fact that patents have issued recognizing the utility of a class of molecules does this confers a statutory precedent of patentability to a broad class of compositions (nucleic acid sequences). Thus, there remains a lingering issue regarding due process and equitable treatment under the law. While Applicants are well aware of the new Utility Guidelines set forth by the USPTO, Applicants respectfully point out that the current rules and regulations regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or

particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotides; **Exhibits 3-5**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples; **Exhibit 6**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), none of which contain examples of the "real-world" utilities that the Examiner appears to desire. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section below), Applicants submit that the present polynucleotides, which encode human zinc metaloproteinase ADAMTS14 an enzyme with well recognized utility, must also meet the requirements of 35 U.S.C. § 101. While Applicants agree that each application is examined on its own merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Applicants invention to a different standard of utility appears inconsistent and inequitable, such a judgement being arbitrary and capricious, a violation of due process and equal protection under the law and cannot be maintained.

In light of the evidence presented herewith and for the many compelling reasons described above, it is clear that the claimed sequences of the present invention encode the human zinc metaloproteinase ADAMTS14 and that the utility of the claimed molecules is specific, substantial, credible and well-established. Therefore, Applicants submit that the rejection of the pending claims under 35 U.S.C. § 101 has been avoided. Applicants, therefore, respectfully request withdrawal of the pending rejection of claims under 35 U.S.C. § 101.

IV. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Action also rejects all claims under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit tha the claimed sequences encoding human zinc metalloproteinase ADAMTS14 have been shown to have "a specific, substantial, and credible utility", as detailed in the preceding section, the rejection under 35 U.S.C. § 112, first paragraph, has been avoided. Applicants therefore request that the rejection of the pending claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claim 2 and 3 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 2 and 3 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed. Cir. 1989); "*Gosteli*") held:

> Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); "*Utter*"), held "(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a

written description of a broadly claimed invention without describing all species that claim encompasses" (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

Further, the Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties" sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; "*Fiers*"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the . . . nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

> In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed

by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself.*

Applicants respectfully submit that Claim 2 (and thus dependent Claim 3) has two limitations, the first being that molecules which encode the amino acid sequence shown in SEQ ID NO: 20; and the second being hybridization under stringent conditions to the nucleotide sequence of SEQ ID NO: 19 or the complement thereof and covered nucleic acid molecules must meet both conditions, not just one. Applicants submit that the nucleic acid molecules identified by the intersection of both parts of Claim 2, those that encode the amino acid sequence shown in SEQ ID NO: 20; and hybridize under stringent conditions to the nucleotide sequence of SEQ ID NO: 19 or the complement thereof, is a finite and well defined group, which those of skill in the art could easily identify and would know how to make and use. Therefore, Applicants respectfully submit that the rejection of Claims 2 and 3 under 35 U.S.C. § 112, first paragraph, is not now nor was it ever proper. Applicants therefore request withdrawal of this rejection.

VI. Rejection of Claims 2 and 3 Under 35 U.S.C. § 112, Second Paragraph

The Non-Final Action next rejects claims 2 and 3 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Non-Final Action rejects claims 2 and 3 as allegedly indefinite over the recitation of "stringent hybridization conditions". First, Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

However, solely in order to progress the case more rapidly toward allowance, Applicants have revised Claim 2 to recite specific "highly stringent hybridization conditions". Applicants submit

that the term "highly stringent hybridization conditions" is sufficiently definite, as exemplary highly stringent hybridization conditions are specifically set forth in the specification (at least at page 4, lines 34-37). Furthermore, a number highly stringent hybridization conditions of would be well known to those of skill in the art. The claims are therefore sufficiently definite when read in light of the specification, which reasonably apprises those skilled in the art both of the utilization and scope of the invention. *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634, 641 (Fed. Cir. 1985). See also *Miles Laboratories, Inc. v. Shandon*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993); *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692, 57 USPQ2d 1293, 1297 (Fed. Cir. 2001); *North American Vaccine, Inc. v. American Cyanamid Co.*, F.3d 1571, 1579, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993); *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986). Providing an admittedly exemplary set of highly stringent hybridization conditions in the specification does not render the claim indefinite, but rather provides guidance to the skilled artisan, without the needless provision of endless recitation of the well known stringent hybridization conditions. As clearly set forth by the Federal Circuit in *S3 v. Nvidia*, 259 F.3d 1364, 59 USPQ2d 1745 (Fed. Cir. 2001):

> The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. *See Vivid Technologies, Inc. v. American Science and Engineering, Inc.*, 200 F.3d 795, 804, 53 USPQ2d 1289, 1295 (Fed. Cir. 1999) ("patents are written by and for skilled artisans"). To hold otherwise would require every patent document to include a technical treatise for the unskilled reader. Although an accommodation to the "common experience" of lay persons may be feasible, it is an unnecessary burden for inventors and has long been rejected as a requirement of patent disclosures. *See Atmel Corp.*, 198 F.3d at 1382, 53 USPQ2d at 1230 (Fed. Cir. 1999) ("The specification would be of enormous and unnecessary length if one had to literally reinvent and describe the wheel."); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983) ("Patents are written to enable those skilled in the art to practice the invention, not the public.").

Thus, Applicants submit that as revised Claim 2 is sufficiently definite, and the rejection of Claims 2 and 3 under 35 U.S.C. § 112, second paragraph is improper and should be withdrawn.

VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Moore have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

July 19, 2004
Date

Lance K. Ishimoto Reg. No. 41,866
Attorney for Applicants

LEXICON GENETICS INCORPORATED
(281) 863-3333

Customer # 24231